John E Klemmer, C.O. 1-23-98

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DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration
CENTRAL REGION

Detroit District Office
1560 East Jefferson Avenue
Detroit, MI 48207-3179
TELEPHONE: 313-226-6260 ext. 178
FACSIMILE: 313-226-3076

CERTIFIED MAIL

RETURN RECEIPT REQUESTED

WARNING LETTER
98-DT-03

January 23, 1998

Tom E. Brandt, President/CEO
Bivona Medical Technologies
5700 West 23rd Avenue
Gary, Indiana 46406-2617

Dear Mr. Brandt:

An inspection of your firm was conducted on December 2 - 12, 1997 by the Food and Drug Administration. The inspection revealed significant deviations from Quality System Requirement Regulations for Medical Devices, Title 21, Code of Federal Regulations, Part 820 (21 CFR 820). These deviations cause your devices, Tracheostomy and Endotracheal Tubes to be in violation of the Federal Food, Drug, and Cosmetic Act (the Act), Section 501(h).

Specifically, the inspection found that there is no written documentation to show that Medical Device Reporting (MDR) standard operating procedures (SOPs) have been developed and implemented as required. In addition, there is no documentation to show that SOPs have been developed and implemented for rework of returned devices. Also, there is no documentation to show that returned products are reworked and/or returned to the customer.

There is no written documentation to show that accuracy and precision limits, and/or any other appropriate limits have been established and maintained for extrusion molding equipment used in processing finished devices at your facility. The specified requirements for ETO sterilization of your finished devices as evidenced in the standard operating procedures for this process, such as gas dwell temperature, and aeration time and temperature is inconsistent with those of the contract supplier of this service.

Documentation of complaint investigations do not appear to always contain accurate information, and/or if no investigation is performed, a reason why the investigation was not performed.

Device History Records (DHRs) for the manufacture of "customized" devices were observed as having been completed prior to the completion of the specific manufacturing process, such as a completed build sheet for the total number of defective devices before all devices for that build sheet had been manufactured. In addition, these DHRs do not contain copies of all labeling used in the packaging of finished devices.

The above is not intended to be an all-inclusive list of deviations which may exist at your firm. It is your responsibility to ensure that your facility is in full compliance with the Act and regulations promulgated thereunder.

We request that you take prompt action to correct these deviations. Failure to make prompt corrections may result in regulatory action without further notice, such as civil penalties, seizure, and/or injunction. In addition, federal agencies are advised of the issuance of all Warning Letters about drugs and devices so that they may take this information into account when considering the award of contracts.

We acknowledge receipt of your December 30, 1997 response to the inspectional observations, however, we find the response incomplete. Your response to observation 2 regarding validation of extrusion molding equipment states that you perform prospective validation of
processes for newly developed components, newly purchase equipment, or process/equipment modifications. You also state that you are performing concurrent validation of components that have been manufactured for some time. You do not state that parameters/limits have been set for the extrusion equipment itself and or parameters/limits have been set for components extruded using the equipment. Concurrent validation cannot be performed on components that have been routinely manufactured, but you may be able to review historical data for a retrospective validation. In any event, this information must be documented, parameters must be established for the equipment and/or components manufactured, and a completion date for this process must be established.

Your response to observation 5 regarding inaccurate Device History Records does not adequately address the problem. While retraining of production personnel is an integral part of addressing this problem, reviewing DHRs prior to product release will not ensure that the problem has been corrected and prevent its recurrence.

Please notify this office in writing, within fifteen (15) working days of your receipt of this letter, of the specific steps you have taken to correct the noted deviations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, please state the reason for the delay, and the time in which the corrections will be completed.

Your response should be directed to this office to the attention of Mrs. Kathleen M. Lewis, Compliance Officer.

Sincerely yours,

for
Raymond V. Mlecko
Acting District Director
Detroit District

cc: Terry Spraker, Ph.D.
President/CEO
UroQuest Medical Corporation
265 East 100 South
Suite 220
Salt Lake City, Utah 84111

cc: EF
HFA-224
HFI-35 (purged)
HFZ-300
HFC-210
HFC-240
HFC-120
DEN-DO (Compliance)
SBRP
Warning Ltr. Bk.